DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 1000123384

Food and Drug Administration
Baltimore District Office
Central Region
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VL #: 05200025

February 4, 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQEUSTED

Dr. Robert I. Shattner, D.D.S., President
The Sporicidin Company
121 Congressional Lane, Suite 600
Rockville, Maryland 20852

Dear Dr. Shattner:

The Food and Drug Administration (FDA) conducted an inspection of your establishment located in Rockville, Maryland, on December 6-15, 2004. Investigators [redacted] and [redacted] have determined that your establishment operates as a specification developer of sterilization and disinfectant products, which are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). At the conclusion of the inspection, a Form FDA 483, Inspectional Observations was issued to you.

The inspection revealed significant violations of Section 501(h) of the FD&C Act, in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformance with the current Good Manufacturing Practice (cGMP) requirements for medical devices which are set forth in the Quality System Regulation (QSR), as specified in Title 21, Code of Federal Regulations (CFR), Part 820. In addition, your medical device, Sporicidin Sterilizing and Disinfecting Solution (SSDS) is misbranded within the meaning of Section 502(f)(1) of the FD&C Act.

The following violations of the Quality System regulation were observed:

1. Management reviews do not ensure that the quality system satisfies the requirements of Part 820 **[21 CFR 820.20(c)]**. Specifically, management reviews performed in 2001, 2002, and 2003 did not reveal that stability studies for the new Sporicidin Sterilizing and Disinfecting Solution formulation were not conducted. Additionally, no management reviews were performed in 2004.

2. Quality audits did not verify that the quality system is effective in fulfilling your quality system objectives **[21 CFR 820.22]**. Specifically, quality audits performed by the firm did not identify the following deficiencies:

    a. no process validation study for the new Sporicidin Sterilizing and Disinfecting Solution formulation was conducted by the contract manufacturer; and

b. no stability studies were conducted for the new Sporicidin Sterilizing and Disinfecting Solution formulation to support the twenty-four (24) month expiration date.

3. Process validation activities and results have not been documented **[21 CFR 820.75(a)]**. Specifically, there is no documentation to support that process validation has been conducted for the new Sporicidin Sterilizing and Disinfecting Solution formulation by the contract manufacturer. Also, there is no documentation to support that process validation has been conducted for Sporicidin Sterilizing and Disinfecting Activator or any other products by the contract manufacturer.

4. Procedures for verifying that design output meets design input were not implemented **[21 CFR 820.30(a)]**. Specifically, there is no documentation that stability testing has been performed to support the validity of a 24 month expiration date for Sporicidin Sterilizing and Disinfecting Solution, following the formulation change in 2000.

5. Procedures to control the design process of the device were not established **[21 CFR 820.30(f)]**. Specifically, design control procedures have not been established by the firm. The firm made changes to the formulation of Sporicidin Sterilizing and Disinfecting Solution in 2000. Between March 2001 and May 2003, [redacted] lots of buffer and [redacted] lots of activator have been manufactured and released for distribution.

6. Procedures were not established for the identification, documentation, validation or verification, review, and approval of design changes before their implementation **[21 CFR 820.30(i)]**. Specifically, [redacted] is incomplete in that it does not provide instructions for the users to evaluate whether the change needs to be evaluated through the design control process.

7. Procedures for acceptance or rejection of finished device production runs, lots, or batches were not implemented **[21 CFR 820.80(d)]**. Specifically, standard operating procedure titled [redacted] states that Sporicidin's Technical Director will review the Certificate of Analysis (COA), (which should include [redacted]) for acceptability before the finished product may be released. The [redacted] result is not listed on the COA received from the contract manufacturer/test laboratory for Sporicidin Sterilizing and Disinfecting Solution-Activator lot numbers [redacted], and [redacted]. The COAs were reviewed by the Technical Director and finished product was released for distribution on [redacted] and [redacted].

8 Acceptance test results of in-process product were not fully documented **[21 820.80(c)]**. Specifically, Sporicidin Sterilizing and Disinfecting Solution Activator repackaging process instructions (dated 3/02/01) states that no repackaging will be performed until specifications are met for [redacted]. The pH result is not listed on the COA received from the contract manufacturer/test laboratory for Sporicidin Sterilizing and Disinfecting Solution-Activator lot numbers [redacted], and [redacted]. The COAs were reviewed and approved by Sporicidin's Technical Director to allow the contractor to package the bulk solutions for distribution.

b. no stability studies were conducted for the new Sporicidin Sterilizing and Disinfecting Solution formulation to support the twenty-four (24) month expiration date.

3. Process validation activities and results have not been documented **[21 CFR 820.75(a)]**. Specifically, there is no documentation to support that process validation has been conducted for the new Sporicidin Sterilizing and Disinfecting Solution formulation by the contract manufacturer. Also, there is no documentation to support that process validation has been conducted for Sporicidin Sterilizing and Disinfecting Activator or any other products by the contract manufacturer.

4. Procedures for verifying that design output meets design input were not implemented **[21 CFR 820.30(a)]**. Specifically, there is no documentation that stability testing has been performed to support the validity of a 24 month expiration date for Sporicidin Sterilizing and Disinfecting Solution, following the formulation change in 2000.

5. Procedures to control the design process of the device were not established **[21 CFR 820.30(f)]**. Specifically, design control procedures have not been established by the firm. The firm made changes to the formulation of Sporicidin Sterilizing and Disinfecting Solution in 2000. Between March 2001 and May 2003, [redacted] lots of buffer and [redacted] lots of activator have been manufactured and released for distribution.

6. Procedures were not established for the identification, documentation, validation or verification, review, and approval of design changes before their implementation **[21 CFR 820.30(i)]**. Specifically, [redacted] is incomplete in that it does not provide instructions for the users to evaluate whether the change needs to be evaluated through the design control process.

7. Procedures for acceptance or rejection of finished device production runs, lots, or batches were not implemented **[21 CFR 820.80(d)]**. Specifically, standard operating procedure titled [redacted] states that Sporicidin's Technical Director will review the Certificate of Analysis (COA), (which should include [redacted]) for acceptability before the finished product may be released. The [redacted] result is not listed on the COA received from the contract manufacturer/test laboratory for Sporicidin Sterilizing and Disinfecting Solution-Activator lot numbers [redacted], and [redacted]. The COAs were reviewed by the Technical Director and finished product was released for distribution on [redacted] and [redacted].

8 Acceptance test results of in-process product were not fully documented **[21 820.80(c)]**. Specifically, Sporicidin Sterilizing and Disinfecting Solution Activator repackaging process instructions (dated 3/02/01) states that no repackaging will be performed until specifications are met for [redacted]. The pH result is not listed on the COA received from the contract manufacturer/test laboratory for Sporicidin Sterilizing and Disinfecting Solution-Activator lot numbers [redacted], and [redacted]. The COAs were reviewed and approved by Sporicidin's Technical Director to allow the contractor to package the bulk solutions for distribution.

9. Adequate quality requirements that must be met by contractors were not implemented **[21 CFR 820.50(a)]**. Specifically, standard operating procedure titled [redacted]' states that audits will be performed on a regular basis every two to four years depending on production. The contract manufacturer/test laboratory for Sporicidin Sterilizing and Disinfecting Solution-Activator was audited and the audit report was reviewed on 9/30/99, with audit follow-up being continuous monitoring of COAs, etc. The COAs for Sporicidin Sterilizing and Disinfecting Solution-Activator were reviewed by Sporicidin's Technical Director for lot numbers [redacted], and [redacted]. The [redacted] result is not listed on the COA received from the contract manufacturer/test laboratory. There is no documentation that the Technical Director contacted the contract manufacturer regarding the missing [redacted] test results. Finished product was released for distribution by Sporicidin's Technical Director.

10. Employees do not have the necessary training to perform their jobs in that there is no documentation that employees of the firm have received training that addresses the quality system regulations **[21 CFR 820.25(a)]**. The firm has not conducted or participated in any QSR training courses, classes, seminars, etc.

Additionally, the above-stated inspection revealed that your device is misbranded under Section 502(f)(1) of the FD&C Act, in that its labeling bares inadequate directions for use because the labeled expiration date has not been established by reliable, meaningful, and specific tests methods, as required by 21 CFR 809.10.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all applicable FDA regulations and the FD&C Act. Federal agencies are advised of the issuance of Warning Letters regarding devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deficiencies. Failure to achieve prompt correction may results in enforcement action without further notice. These actions may include injunction, seizure, and/or civil penalties.

Please notify this office in writing, within (15) fifteen working days of receipt of this letter. Your response should include: (1) the specific steps you have taken to correct the noted violations and to prevent their recurrence; (2) the time within which the corrections will be completed; (3) any reason the corrective actions have not been completed within the response time; and (4) any documentation necessary to show that corrections have been achieved. Your reply should be sent to the Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Ms. Vinetta Howard-King, Compliance Officer. Ms. Howard-King can be reached at (410) 779-5454, extension 413.

Sincerely,

Lee Bowers
Director, Baltimore District